



PATENT  
Attorney Docket No.: JHU1120-13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lee and McPherron Art Unit: 1633  
Application No.: 09/640,887 Examiner: B. Puri  
Filed: August 17, 2000  
Title: GROWTH DIFFERENTIATION FACTOR-8 NUCLEIC ACID AND  
POLYPEPTIDE FROM AQUATIC SPECIES, AND TRANSGENIC  
AQUATIC SPECIES

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Commissioner for Patents  
Washington, D.C. 20231

TECH CENTER 1600/2900

RESPONSE TO THE RESTRICTION REQUIREMENT

Sir:

Responsive to the Office Communication mailed November 20, 2001, in connection with the above-identified patent application, consideration of the following remarks is respectfully requested.

A. Regarding the Restriction Requirement

It is alleged in the Communication that the claims are directed to six independent and patentably distinct inventions, which the Examiner has set forth as Groups I to VI, as follows:

**Group I:** Claims 1 to 15, directed to transgenic organisms, to a method for producing food products from an aquatic organism having increased muscle mass, and to a method of producing a transgenic aquatic organism;

**Group II:** Claims 16 to 17, directed to a method of producing aquatic organism food products having reduced cholesterol levels;

**Group III:** Claims 18 to 20 and 53, directed to a method for increasing the muscle mass in an aquatic organism by administering an antibody that binds to GDF-8 polypeptide to the organism, and to an antibody that binds GDF-8;

CERTIFICATION UNDER 37 CFR §1.8
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, January 22, 2002, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.
Aldon Griffis (Name of Person Mailing Paper)
<i>Aldon Griffis</i> (Signature) <span style="float: right;">January 22, 2002 (Date)</span>

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**Group IV:** Claims 21 to 37, directed to isolated polynucleotides encoding a GDF-8 having 65% identity to murine GDF-8 polypeptide;

**Group V:** Claims 38 to 43, directed to isolated polynucleotides encoding a GDF-8 polypeptide and to a nucleotide sequences that hybridize to such polynucleotides; and

**Group VI:** Claims 44 to 52, directed to purified GDF-8 polypeptide from an aquatic organism.

Although Applicants traverse the restriction requirement for the reasons set forth below, Applicants nevertheless elect the claims of Group I, claims 1 to 15, for examination in order to be fully responsive to the Communication.

The restriction requirement is traversed generally with respect to all of Groups I to IV because there is no indication in the Communication as to the Class or Sub-class that would be required of a search for any of the Groups. As such, while the claims of each group are independent and patentably distinct, there is no objective basis for dividing the claims into the six Groups shown, or, therefore, to argue whether two or more of the Groups as set forth in the Communication reasonably can be examined together without creating an undue burden on the Examiner. Accordingly, it is respectfully requested that the claims of the Groups be rejoined and examined together or, alternatively, that an indication of the classifications supporting the division of the claims into Groups I to VI be provided.

The restriction requirement is traversed in particular as to the claims of Groups I and II. Specifically, Applicants point out that the methods for producing transgenic aquatic organisms having "increased muscle mass" (claims 7 and 8) are substantially similar to the methods for producing transgenic organisms having "reduced cholesterol levels" (claim 16). As such, it is submitted that a search of the methods encompassed within Group I and those encompassed within Group II would necessarily require duplicative searches and, therefore, it would not

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constitute an undue burden for the Examiner to rejoin the claims of Groups I and II and examine them together. Accordingly, absent an indication as to the Class and Sub-class supporting the division of the claims of Groups I and II, it is respectfully requested that the claims of Groups I and II be rejoined and examined together.

**B. Regarding the Species Election**

It is further alleged that the aquatic animals set forth in Claim 2 (crustacean, mollusk, chordate, gastropod, pelecypod, cephalopod, and echinoderm) constitute an independent and patentably distinct species from the aquatic animals of Claim 3 (piscine and amphibian), and requested that an election of one of the species be made.

Although Applicants traverse the requirement to elect a species for the reasons set forth below, in order to be fully responsive to the Action, Applicants elect the species of claim 3 (piscine and amphibian) for examination. It is noted that claims 1, 3 to 13, 15 to 27, 29 to 46, and 48 to 53 read on the elected species.

The requirement to elect a species is traversed because there is no reason set forth in the Office Communication to support the species election. Applicants submit that, while the species as set forth are independent and patentably distinct, the species set forth, for example, in claim 2 and in claim 3 share a commonality of operation, function and effect (MPEP § 806.04(e)) with respect to the claimed transgenic organisms and methods of generating such organisms. Specifically, the transgenic organisms all share a common disruption of a GDF-8 gene, and the methods are all directed to disrupting the GDF-8 gene and identifying transgenic organism that have increased muscle mass (claims 7 and 8) or reduced cholesterol levels (claim 16). As such, it is submitted that an election of one species should not be required and that the transgenic organisms as set forth in claim 2 and claim 3, and methods of generating such organisms, should be examined together.

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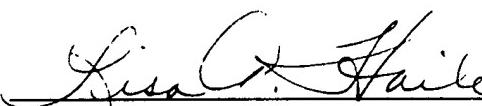
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In summary, the claims of Group I, claims 1 to 15, and the species of organisms set forth in claim 3, Piscine and amphibian, are provisionally elected for examination. However, for the reasons set forth above, it is respectfully requested that the Examiner reconsider the restriction requirement, particularly with respect to the claims of Group I and Group II, and reconsider the species election requirement, and rejoin and examine the claims together.

The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application. The Commissioner is authorized to charge any additional fees that may be required, or credit any overpayments, to Deposit Acct. No. 50-1355.

Respectfully submitted,

Dated: January 22, 2002

  
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